

### **REMARKS**

This is a full and timely response to the outstanding Office Action mailed March 24, 2006. Upon entry of the amendments in this response, claims 1 - 13 remain pending. In particular, Applicant has amended claims 1, 3, 7 and 12. Reconsideration and allowance of the application and presently pending claims are respectfully requested.

#### **I. Present Status of Patent Application**

Claims 1 - 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by *Steiner* et al. (US 5,499,984). Claims 1 - 6 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Boucher* et al. (US 6,716,216). Claims 1 - 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Bonutti* (US 5,269,785) in view of *Boucher* et al. (US 6,716,216). In response, claims 1, 3, 7 and 12 are amended. Support can be found in, for example, page 3, lines 13-20; page 5, lines 7-19; page 8, lines 5-17; page 8, line 20- page 9, line 5; page 9, line 21- page 10, line 14; and/or Fig.6-8 of the present application. No new matter is added. Therefore, these rejections are respectfully traversed.

#### **II. Rejections Under 35 U.S.C. §102(b)**

The Office Action rejects claims 1-6 under 35 U.S.C. §102(b) as allegedly being anticipated by *Steiner* et al. (US 5,499,984). Specifically, the Office alleges that “*Steiner* et al. disclose a flexible tap apparatus member (20, 30) including a flexible upper shaft portion including ridges 21 and a flexible lower shaft portion that is coupled to an adaptor or ‘handle’ 33 (Fig. 1 and 10, col. 3, lines 31-67, col. 4, lines 1-50 and col. 5, lines 41-47).” (Office Action, p. 2). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

**Independent claim 1** as amended recites:

1. A flexible tap apparatus member comprising:  
a shaft having a *flexible upper shaft portion* and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;

wherein *said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in the tissue.*

(Emphasis Added).

For a proper rejection of a claim under 35 U.S.C. §102, the cited reference must disclose, teach, or suggest all elements/features/steps of the claim at issue. *See, e.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988).

Applicant respectfully submits that *Steiner* is legally deficient for the purpose of anticipating claim 1. In particular, Applicant respectfully asserts that independent claim 1 as amended is allowable for at least the features/limitations emphasized above in claim 1. That is, *Steiner* neither discloses **a flexible upper shaft portion**, nor does *Steiner* disclose **a flexible tap apparatus member arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in the tissue.** As explained in the present application,

The introduction of a pedicle screw to a vertebral body can result in various complications, including but not limited to the “break-out” of the pedicle screw through the pedicle wall. . . . [P]articularly in the thoracic and lumbar spine, eighty percent of the pull out strength is obtained by the fit of the pedicle screw into the pedicle. . . . Insertion of rigid members, such the pedicle screw and a typical pedicle tap, into a pedicle that are of such a desired size can result in perforation of the pedicle.

(See *Application*, page 2, lines 8-20).

Therefore, as disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

(See *Application*, page 5, lines 15-18).

*Steiner* is substantially different from claim 1 of the present application in many aspects. First, the Office seems to compare *Steiner*'s cutting head 20 with the claimed flexible upper shaft portion. *Steiner*, however, never discloses the cutting head 20 to be flexible. Moreover, the Office seems to compare *Steiner*'s cutting head 20 and shaft 30 with the claimed flexible tap apparatus member comprising flexible upper and lower shaft portions. *Steiner*'s system, however, is not disclosed to and cannot be used to remain anchored in the tissue after insertion into a living body for at least two independent reasons.

First, *Steiner*'s system is not designed to remain anchored in the tissue after its insertion into the body. *Steiner*'s system is a "medullary reaming system[]" merely "used to enlarge the medullary canals of bone" (col. 1, lines 6-11). Though *Steiner* discloses a "flexible drive shaft[]" (col. 1, line 7) as shown in Fig. 1, the flexible drive shaft 30 is designed to couple to a "source of rotational drive power" "for rotating the shaft [30] about its axis . . ." (col. 4, lines 13-16). Besides, *Steiner*'s drive shaft 30 is included to deal with the curvature nature of the medullary canals of bone. ("The medullary canals of bone typically have some degree of **curvature** and, **for this reason**, are almost always prepared with reamers having a flexible shaft" (col. 1, lines 6-11)). Therefore, *Steiner* is substantially different from claim 1 of the present application

Second, the preferred length of *Steiner*'s drive shaft 30 also makes itself unsuitable to remain anchored in the tissue after insertion into the body. In a preferred embodiment, the present application discloses that "[f]or example, the tap apparatus members 10 can expand from a 2.5mm length to a 5.0mm length . . ." in order to be able to remain engaged with tissue after insertion (see *Application*, page 7, lines 22-23). *Steiner*, however, discloses that the drive shaft 30 "may typically be in the range of from 12 to 20 inches" (col. 3, lines 64-65). It cannot be reasonably expected that *Steiner*'s system (20, 30) of at least 12 inches can remain anchored in the tissue after its insertion into the body. Therefore, *Steiner* is substantially different from claim 1 of the present application.

Therefore, *Steiner* does not anticipate independent claim 1, and the rejection should be withdrawn. Because independent claim 1 is allowable over the cited references of record, dependent claims 2-6 (which depend from independent claim 1) are allowable as a matter of law for at least the reason that dependent claims 2-6 contain all the steps/features of independent

claim 1. *See Minnesota Mining and Manufacturing Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299 (Fed. Cir. 2002) *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 54 U.S.P.Q.2d 1086 (Fed. Cir. 2000); *Wahpeton Canvas Co. v. Frontier Inc.*, 870 F.2d 1546, 10 U.S.P.Q.2d 1201 (Fed. Cir. 1989). Therefore, since dependent claims 2-6 are patentable over *Steiner*, the rejection to claims 2-6 should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claim 1, dependent claims 2-6 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patently distinct from the cited references of record. Hence there are other reasons why dependent claims 2-6 are allowable.

Reconsideration of the rejections of claims 1-6 is hereby requested.

### **III. Rejections Under 35 U.S.C. §102(e)**

The Office Action rejects claims 1-6 under 35 U.S.C. §102(e) as allegedly being anticipated by *Boucher et al.* (US 6,716,216). Specifically, the Office alleges that “Boucher et al. disclose a flexible tap apparatus member including an upper shaft portion having ridges 88, a lower shaft portion having a substantially smooth surface, an axial passage extending along the flexible shaft and a handle 80 configured to receive the lower shaft portion (Figs. 16D and 18A-C, col. 13, lines 62-67 and col. 14, lines 1-23).” (Office Action, p. 2). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

**Independent claim 1** as amended recites:

1. A flexible tap apparatus member comprising:  
a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;  
wherein *said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in the tissue.*

(Emphasis Added).

For a proper rejection of a claim under 35 U.S.C. §102, the cited reference must disclose, teach, or suggest all elements/features/steps of the claim at issue. *See, e.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988).

Applicant respectfully submits that *Boucher* is legally deficient for the purpose of anticipating claim 1. In particular, Applicant respectfully asserts that independent claim 1 as amended is allowable for at least the features/limitations emphasized above in claim 1. That is, *Boucher* does not disclose **a flexible tap apparatus member arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in the tissue**. As explained in the present application,

The introduction of a pedicle screw to a vertebral body can result in various complications, including but not limited to the “break-out” of the pedicle screw through the pedicle wall. . . . [P]articularly in the thoracic and lumbar spine, eighty percent of the pull out strength is obtained by the fit of the pedicle screw into the pedicle. . . . Insertion of rigid members, such the pedicle screw and a typical pedicle tap, into a pedicle that are of such a desired size can result in perforation of the pedicle.

(*See Application*, page 2, lines 8-20).

Therefore, as disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

(*See Application*, page 5, lines 15-18).

*Boucher* is substantially different from claim 1 of the present application because *Boucher's* system is not disclosed to and cannot be used to remain anchored in the tissue after insertion into the body. The Office seems to compare *Boucher's* drill bit instrument 88 and cutting edge 90 with the claimed flexible upper shaft portion. Applicant responds in the same vein. As shown in its Figs. 16D-E and/or Figs.18A-C, *Boucher's* system includes a drill bit

instrument 88 having a cutting edge 90 for “rotating cutting force to bone” (col. 14, line 7) to form lateral passage PLA (Fig. 16E). *Boucher* further explains,

Once the passage PLA in cancellous bone 32 has been formed, the physician **removes the drill bit instrument 88** and the guide pin instrument 76, leaving only the cannula instrument 84 in place, as FIG. 16E shows. The passage PLA made by the drill bit instrument 88 remains. Subcutaneous lateral access to the cancellous bone 32 has been accomplished.

(*Boucher*’s col. 14, lines 30-36, Emphasis Added).

It is clear that *Boucher*’s drill bit instrument 88 having a cutting edge 90 is not designed to remain anchored in the tissue after its insertion into the body, but rather must be **removed** after its drilling purpose has been accomplished. Therefore, *Boucher* is substantially different from claim 1 of the present application.

Therefore, *Boucher* does not anticipate independent claim 1, and the rejection should be withdrawn. Because independent claim 1 is allowable over the cited references of record, dependent claims 2-6 (which depend from independent claim 1) are allowable as a matter of law for at least the reason that dependent claims 2-6 contain all the steps/features of independent claim 1. *See Minnesota Mining and Manufacturing Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299 (Fed. Cir. 2002) *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 54 U.S.P.Q.2d 1086 (Fed. Cir. 2000); *Wahpeton Canvas Co. v. Frontier Inc.*, 870 F.2d 1546, 10 U.S.P.Q.2d 1201 (Fed. Cir. 1989). Therefore, since dependent claims 2-6 are patentable over *Boucher*, the rejection to claims 2-6 should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claim 1, dependent claims 2-6 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patently distinct from the cited references of record. Hence there are other reasons why dependent claims 2-6 are allowable.

Reconsideration of the rejections of claims 1-6 is hereby requested.

#### IV. Rejections Under 35 U.S.C. §103(a)

The Office Action rejects claims 1-13 under 35 U.S.C. §103(a) as allegedly being unpatentable over *Bonutti* (US 5,269,785) in view of *Boucher* et al. (US 6,716,216). For at least the reasons set forth below, Applicant respectfully traverses the rejection.

##### A. Independent Claim 1

Independent claim 1 as amended recites:

1. A flexible tap apparatus member comprising:  
a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;  
wherein *said flexible tap apparatus member is arranged and configured such that after insertion into a living body, said upper shaft portion is anchored in the tissue.*

(Emphasis Added).

Applicant respectfully submits that independent claim 1 is allowable for at least the reason that claim 1 is not rendered obvious under *Bonutti*, *Boucher*, or their combination. As explained in the present application,

The introduction of a pedicle screw to a vertebral body can result in various complications, including but not limited to the “break-out” of the pedicle screw through the pedicle wall. . . .  
[P]articularly in the thoracic and lumbar spine, eighty percent of the pull out strength is obtained by the fit of the pedicle screw into the pedicle. . . . Insertion of rigid members, such the pedicle screw and a typical pedicle tap, into a pedicle that are of such a desired size can result in perforation of the pedicle.

(See *Application*, page 2, lines 8-20).

Therefore, as disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable

direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

(See *Application*, page 5, lines 15-18).

The combination of *Bonutti* and *Boucher* is substantially different from claim 1 of the present application in several aspects. First, as shown in its Figs. 1, 3 and/or Figs.14A-E indicated by the Office, *Bonutti*'s "percutaneous bone removal apparatus" includes a flexible drill 12 having a flexible shaft 14 and a cutting tip 16 at the distal end of the shaft 14" (col. 5, lines 25-28). *Bonutti*, however, never discloses its cutting tip 16 to be flexible. Moreover, as evident from *Bonutti*'s Fig. 1, *Bonutti*'s apparatus is not disclosed to and cannot be used to remain anchored in the tissue after insertion into the body. As already explained in the above, *Boucher*'s system and drill bit instrument 88 also suffer similar deficiency. Therefore, claim 1 is substantially different from *Bonutti*, *Boucher*, or their combination and is not rendered obvious accordingly.

**B. Independent Claim 7**

Independent claim 7 as amended recites:

7. A flexible tap apparatus system comprising:
  - a first flexible tap apparatus member, comprising:
    - a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;
    - wherein said shaft of said first flexible tap apparatus member comprises a first set of dimensions; and
  - a second flexible tap apparatus member, comprising:
    - a shaft having a flexible upper shaft portion and a flexible lower shaft portion, said upper shaft portion comprising ridges and said lower shaft portion having a substantially smooth surface;
    - wherein said shaft of said second flexible tap apparatus member comprises a second set of dimensions;
  - wherein said first set of dimensions differs from said second set of dimensions, and wherein *at least one of said flexible tap apparatus members is arranged and configured such that*



***after insertion into a living body, said upper shaft portion of said flexible tap apparatus member is anchored in the tissue.***

(Emphasis Added).

Applicant respectfully submits that independent claim 7 is allowable for at least the reason that claim 7 is not rendered obvious under *Bonutti*, *Boucher*, or their combination. As explained in the present application,

The introduction of a pedicle screw to a vertebral body can result in various complications, including but not limited to the “break-out” of the pedicle screw through the pedicle wall. . . . [P]articularly in the thoracic and lumbar spine, eighty percent of the pull out strength is obtained by the fit of the pedicle screw into the pedicle. . . . Insertion of rigid members, such the pedicle screw and a typical pedicle tap, into a pedicle that are of such a desired size can result in perforation of the pedicle.

(See *Application*, page 2, lines 8-20).

Therefore, as disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

(See *Application*, page 5, lines 15-18).

The combination of *Bonutti* and *Boucher* is substantially different from claim 7 of the present application in several aspects. First, as shown in its Figs. 1, 3 and/or Figs.14A-E indicated by the Office, *Bonutti*'s “percutaneous bone removal apparatus” includes a flexible drill 12 having a flexible shaft 14 and a cutting tip 16 at the distal end of the shaft 14” (col. 5, lines 25-28). *Bonutti*, however, never discloses its cutting tip 16 to be flexible. Moreover, as evident from *Bonutti*'s Fig. 1, *Bonutti*'s apparatus is not disclosed to and cannot be used to remain anchored in the tissue after insertion into the body. As already explained in the above, *Boucher*'s

system and drill bit instrument 88 also suffer similar deficiency. Therefore, claim 7 is substantially different from *Bonutti*, *Boucher*, or their combination and is not rendered obvious accordingly.

**C. Independent Claim 12**

Independent claim 12 as amended recites:

12. A method of creating a passage in tissue comprising:  
providing a flexible tap apparatus system comprising:  
a first flexible tap apparatus member, comprising:  
a shaft having a flexible upper shaft portion and a  
flexible lower shaft portion, said upper shaft  
portion comprising ridges and said lower  
shaft portion having a substantially smooth  
surface;  
wherein said shaft of said first flexible tap apparatus  
member comprises a first set of dimensions;  
and  
a second flexible tap apparatus member, comprising:  
a shaft having a flexible upper shaft portion and a  
flexible lower shaft portion, said upper shaft  
portion comprising ridges and said lower  
shaft portion having a substantially smooth  
surface;  
wherein said shaft of said second flexible tap  
apparatus member comprises a second set of  
dimensions;  
wherein said first set of dimensions differs from said  
second set of dimensions;  
engaging said first flexible tap apparatus member into the tissue;  
disengaging said first flexible tap apparatus member from the  
tissue; and  
engaging said second flexible tap apparatus member into the tissue  
so that ***said second flexible tap apparatus member is  
arranged and configured such that after insertion into a  
living body, said upper shaft portion of said flexible tap  
apparatus member is anchored in the tissue.***

(Emphasis added).

Applicant respectfully submits that independent claim 12 is allowable for at least the reason that claim 12 is not rendered obvious under *Bonutti*, *Boucher*, or their combination. As explained in the present application,

The introduction of a pedicle screw to a vertebral body can result in various complications, including but not limited to the “break-out” of the pedicle screw through the pedicle wall. . . .

[P]articularly in the thoracic and lumbar spine, eighty percent of the pull out strength is obtained by the fit of the pedicle screw into the pedicle. . . . Insertion of rigid members, such the pedicle screw and a typical pedicle tap, into a pedicle that are of such a desired size can result in perforation of the pedicle.

(See *Application*, page 2, lines 8-20).

Therefore, as disclosed in the present application, in at least one exemplary embodiment,

[I]t is desirable that both the upper shaft portion 16 and the lower shaft portion 18 are flexible to reduce the likelihood of breakout from a pedicle. The shaft portion 18 can be flexible in any suitable direction, such as from side-to-side, or to alter length of the tap apparatus member 10.

(See *Application*, page 5, lines 15-18).

The combination of *Bonutti* and *Boucher* is substantially different from claim 12 of the present application in several aspects. First, as shown in its Figs. 1, 3 and/or Figs.14A-E indicated by the Office, *Bonutti*’s “percutaneous bone removal apparatus” includes a flexible drill 12 having a flexible shaft 14 and a cutting tip 16 at the distal end of the shaft 14” (col. 5, lines 25-28). *Bonutti*, however, never discloses its cutting tip 16 to be flexible. Moreover, as evident from *Bonutti*’s Fig. 1, *Bonutti*’s apparatus is not disclosed to and cannot be used to remain anchored in the tissue after insertion into the body. As already explained in the above, *Boucher*’s system and drill bit instrument 88 also suffer similar deficiency. Therefore, claim 12 is substantially different from *Bonutti*, *Boucher*, or their combination and is not rendered obvious accordingly.

**D. Other Dependent Claims**

Because independent claims 1, 7 and 12 are allowable over the cited references of record, dependent claims 2-6, 8-11 and 13 (which depend from independent claims 1, 7 or 12) are allowable as a matter of law for at least the reason that dependent claims 2-6, 8-11 and 13 contain all the features/steps of their respective independent claim. *See Minnesota Mining and Manufacturing Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299 (Fed. Cir. 2002) *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 54 U.S.P.Q.2d 1086 (Fed. Cir. 2000); *Wahpeton Canvas Co. v. Frontier Inc.*, 870 F.2d 1546, 10 U.S.P.Q.2d 1201 (Fed. Cir. 1989). Therefore, since dependent claims 2-6, 8-11 and 13 are patentable over *Bonutti*, *Boucher*, or their combination, the rejection to those claims should be withdrawn and the claims allowed.

Additionally and notwithstanding the foregoing reasons for allowability of independent claims 1, 7 and 12, dependent claims 2-6, 8-11 and 13 recite further features and/or combinations of features, as are apparent by examination of the claims themselves, that are patently distinct from the cited references of record. Take claim 3 as an example. Dependent claim 3 as amended recites:

3. The flexible tap apparatus member of claim 1, further comprising:  
***a guide pin*** for being removably disposed in the tissue to ***align said flexible tap apparatus member***; and  
***a passage*** disposed axially into said shaft, ***through which the guide pin is removably engaged***.

(Emphasis added).

Applicant respectfully submits that dependent claim 3 as amended is allowable for at least the additional features/limitations emphasized above. That is, none of the cited prior art discloses **a guide pin for being removably disposed in the tissue to align said flexible tap apparatus member and a passage disposed axially into said shaft, through which the guide pin is removably engaged**. For example, *Boucher* discloses a guidewire 182 in its FIG. 18B, which “can be pre-bent, to alter the path of the cutting edge 90 after [the cutting edge 90] enters the vertebral body” (col. 14, lines 12-14). It is clear that *Boucher*’s guidewire 182 in FIG. 18B

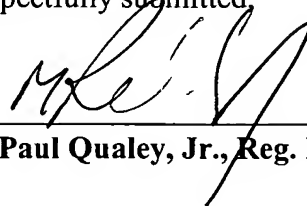
functions the same as its “deflector element 94” to “**flex** the flexible shaft portion 92 and guide the cutting edge 90 along a desired drill axis” (col. 13, line 67 - col. 14, line 2) (emphasis added). *Boucher’s* guidewire 182 therefore is different from the guide pin for **being removably disposed in the tissue to align** said flexible tap apparatus member, as recited in claim 3.

Hence there are other reasons why claim 3 and other dependent claims are allowable. Reconsideration of the rejections of claims 1-13 is hereby requested.

### CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1-13 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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